K080661

510(k) Summary

As Required by 21 section 807.92 (c)

MAR 24 2008

1-Submitter Name: Koalaty Products, Inc
2-Address: 5015 N. Clark Ave.
Tampa, FL 33614
3-Phone: 813 871 5901
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5-Contact Person: Mr Jeff Lenoir (President)
6-Date summary prepared: September 7th, 2007
7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12-Device Trade or Proprietary Name:
(a) TENS (Model TENS 7000)
(b) EMS (Model EMS 7500)
(c) TENS/EMS (Model TWIN STIM)
13-Device Common or usual name:
(a) TENS UNIT
(b) EMS UNIT
(c) TENS/EMS COMBINATION UNIT
14-Device Classification Name:
(a) Stimulator, nerve, transcutaneous, for pain relief
(b) Stimulator, muscle, powered
(c) Combination of (i) Stimulator, nerve, transcutaneous, for pain relief **AND** (ii) Stimulator, muscle, powered
15-Substantial Equivalency is claimed against the following device:
Models EV-804, EV-805 and EV-806 from Everyway Medical Instruments Co., Ltd. 510k# K020749, 510k #K071951

16-Description of the Device:

This series, which includes models TENS 7000, EMS 7500, and TWIN STIM, are Transcutaneous Electrical Nerve Stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The parameters of units are controlled by the press buttons. Its intensity level is adjustable according to the needs of patients.

The three models have the same housing. The process to set the parameter and attach lead wires to the unit are also the same. Yet, they have different liquid crystal display and parameters for patients to create their own settings.

The TENS 7000 is a TENS device with 5 modes and adjustable pulse rate, pulse width and timer. The EMS 7500 is an EMS device with 3 modes and adjustable pulse rate, pulse width, contraction time, relaxation time, ramp time and timer. The TWIN STIM is a combination unit with both TENS and EMS functions. The

function can be selected by press buttons. The range of settings are identical to those of TENS 7000 and EMS 7500. The difference on the three units can be identified by the liquid crystal display.

17-Intended use of the device: (refer to FDA form attached)

The intended Use of TENS 7000 is as follows:
This device is an electrical nerve stimulator intended for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is intended for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems

The Intended Use of EMS 7500 is as follows:
This device is an electrically powered muscle stimulator intended for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is intended for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy

The Intended Use of TWIN STIM are as follows:
This combination device is intended for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is intended for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems

It is also intended for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is intended for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy

18-Safety and Effectiveness of the device:

This series is safe and effective as the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Koalaty Products, Incorporated
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

MAR 24 2008

Re: K080661
Trade/Device Name: Models TENS 7000, EMS 7500 and Twin Stim
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: March 7, 2008
Received: March 10, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: TENS 7000, EMS 7500 and TWIN STIM

Indications For Use:

APPLICABLE FOR TENS 7000 AND TWIN STIM:

This device is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for (1) Symptomatic relief and management of chronic (long term) intractable pain and (2) adjunctive treatment in the management of post surgical and post traumatic pain problems

APPLICABLE FOR EMS 7500 and TWIN STIM:

This device is an electrically powered muscle stimulator indicated for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is indicated for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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